**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF OHIO**
**EASTERN DIVISION**

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| IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION | |
| This document relates to: | MDL No. 2804 |
| *The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.*, Case No. 18-op-45090 | Hon. Dan Aaron Polster |
| *The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al.*, Case No. 17-op-45004 | |

**DEFENDANTS' *DAUBERT* ROADMAP REPLY BRIEF**

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## INTRODUCTION

Plaintiffs' response to Defendants' roadmap brief understandably seeks to lower the *Daubert* bar, suggesting that the Court can phone in its gatekeeper function and admit expert testimony that is plainly irrelevant, unreliable, and speculative. But *Daubert* requires more and under Supreme Court and Sixth Circuit precedent, the Court has an obligation to give the proposed testimony a hard look and ensure that Rule 702's standards are satisfied and that the opinions do not unfairly prejudice Defendants or confuse the jury under Rule 403. The Court should reject Plaintiffs' invitation to abdicate that duty.

With respect to their experts, Plaintiffs have now abandoned many of their opinions rather than defend them, and otherwise hope that the law of low expectations will let the rest slip through the cracks. As discussed briefly below—and more thoroughly in the accompanying Reply briefs supporting Defendants' motions to exclude targeted expert testimony on causation, liability, and damages—Plaintiffs have failed to meet their burden of proffering qualified experts and/or reliable opinions. To ensure the integrity of the trial, the Court should exclude all such testimony.

## I. REPLY TO PLAINTIFFS' MISCHARACTERIZATION OF *DAUBERT*

### A. Plaintiffs Seek to Impermissibly Lower the *Daubert* Bar

Plaintiffs do not take serious issue with the *Daubert* standard set forth in Defendants' roadmap brief, but instead seek to supplement and water down the inquiry, effectively urging the Court to rubberstamp their experts. Plaintiffs argue that the Court can overlook the myriad defects with their experts' opinions because courts are permitted to allow "shaky" expert opinions, Pls. Br. 4, or expert analysis that has "weaknesses," is not "accurate," has "not been peer reviewed," or is based on "undependable" facts or methodological "flaws." *Id.* at 4, 6. They argue that courts can look the other way when the expert has "a lack of specialization" in the field, *id.* at 4-5, or a "lack of familiarity with some aspects of the subject matter." *Id.* at 5. In their effort to lower the

bar, Plaintiffs offer seven *Daubert* "concepts" supposedly omitted by Defendants that they say warrant admission of their experts' testimony. Plaintiffs' slanted take on the law aside, none of the seven concepts permits the improper expert opinions proposed by Plaintiffs.

### B. Plaintiffs' Seven "Concepts" Misstate *Daubert*

#### 1. The Court's Gatekeeping Function Does Not "Replace the Adversary System"

Plaintiffs suggest that no matter how flawed, how irrelevant, or how prejudicial an expert's testimony may be, all can be forgiven since the adversary system affords the right to cross-examine the experts. Pls. Br. 4-5. But that ignores the Court's role in the process. Federal Rule of Evidence 702 requires courts to engage in a "close judicial analysis" of an expert's opinion. *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 252 (6th Cir. 2001) (quoting *Turpin v. Merrell Dow Pharm.*, 959 F.2d 1349, 1352 (6th Cir. 1992)). Declining to fulfill this charge is reversible error. *See Estate of Barabin v. AstenJohnson, Inc.*, 740 F.3d 457, 464 (9th Cir. 2014) ("Just as the district court cannot abdicate its role as gatekeeper, so too must it avoid delegating that role to the jury.").

Close scrutiny of proffered expert testimony is needed not only "because of the likelihood of juror misunderstanding, but also because expert witnesses are not necessarily always unbiased scientists." *Id.* As the Sixth Circuit has explained, "a court does not depart from its proper function" when it takes a "hard look" at expert testimony. *Turpin*, 959 F.2d at 1353; *see also Weisgram v. Marley Co.*, 528 U.S. 440, 455 (2000) (describing the *Daubert* inquiry as "exacting"). To be sure, some flaws in expert opinions go to weight, not admissibility. But where, as here, the opinions fail to satisfy the baseline requirements of Rule 702 and *Daubert*, a court has a duty to step in. Otherwise, *Daubert* would be nothing more than an empty formality.

**2. An Expert's Conclusions Are Not Irrelevant to the *Daubert* Inquiry**

Plaintiffs argue that "[n]othing in Rule 702 or *Daubert* and its progeny, or in the rulings of the Sixth Circuit permits this Court to subject an expert's conclusions . . . to the *Daubert* analysis." Pls. Br. 6. In support of this assertion they quote *Daubert*'s observation that "the focus . . . must be solely on the principles and methodology, not on the conclusions that they generate." *Id.* at 5 (quoting *Daubert*, 509 U.S. at 595). But Plaintiffs fail to mention the Supreme Court's post-*Daubert* clarification that "conclusions and methodology are not entirely distinct from another." *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). Indeed, courts have an *obligation* to assess and exclude unreliable conclusions under Rule 702 and *Daubert*. *See McLean v. 988011 Ontario, Ltd.*, 224 F.3d 797, 801 (6th Cir. 2000).

The Supreme Court's decision in *General Electric Co. v. Joiner* is instructive. There, an electrician developed lung cancer after certain chemicals "would sometimes splash onto him, occasionally getting into his eyes and mouth." 522 U.S. at 139. The electrician sued the chemical manufacturers, and sought to introduce expert testimony that the chemicals caused his cancer. *Id.* at 518. The expert based his conclusion on an animal study in which "massive doses" of the chemicals were injected directly into the stomachs of infant mice, and failed to explain how the study established causation at real-world exposure levels. *Id.* The expert also relied on four epidemiological studies: The first rejected the expert's causal conclusion, the second did not find a statistically significant link, the third did not consider the relevant chemical, and the fourth involved subjects exposed to other carcinogens. *Id.* at 144-46. Rejecting the exact same argument Plaintiffs advance here about the purported need to avoid scrutinizing conclusions, *id.* at 146, the Supreme Court held the testimony was properly excluded. It explained that while "[t]rained experts commonly extrapolate from existing data," courts should not admit conclusions that are "connected to existing data only by the *ipse dixit* of the expert." *Id.* "A court may conclude that

there is simply too great an analytical gap between the data and the opinion proffered." *Davis v. McKesson Corp.*, No. CV-18-1157-PHX-DGC, 2019 WL 3532179, at *4 (D. Ariz. Aug. 2, 2019) (quoting *Joiner*, 522 U.S. at 146). Plaintiffs' expert conclusions are thus not immune from this Court's *Daubert* inquiry. To the contrary, the failure to consider the experts' *ipse dixit* conclusions would constitute reversible error.

**3. An Expert Cannot Rely on Facts Inconsistent with Record Evidence**

Plaintiffs assert that "the facts on which the expert bases his opinions need not be in the record." Pls. Br. 6. But that does not give an expert carte blanche to rely, as with Plaintiffs' experts, on factual premises or assumptions that are incorrect, implausible, or inconsistent with the record. *See In re Southeastern Milk Antitrust Litig.*, 739 F.3d 262, 280 (6th Cir. 2014). For example, in *Matsushita Elec. Indus. Co. v. Zenith Radio Corp*, the Supreme Court affirmed a lower court's decision to exclude an expert report that utilized assumptions about a competitor's costs because the assumptions were "implausible and inconsistent with record evidence." 475 U.S. 574, 594 & n.19 (1986). The Sixth Circuit has similarly explained that "an expert's opinion must use valid facts to be reliable." *In re Southeastern Milk*, 739 F.3d at 280 (citing *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993)). Experts therefore cannot base their opinions on analytical models that use "implausible" inputs—such as an assumption that *all* of Defendants' marketing of prescription opioid medications was unlawful. Such testimony is unreliable and therefore cannot properly be admitted. *Matsushita*, 475 U.S. at 594 & n.19.

**4. The Expert Testimony Here Falls into the Exception, Not the Rule**

Plaintiffs also argue that exclusion of expert testimony "is the exception rather than the rule." Pls. Br. 4. This axiom, however, does not excuse a party from meeting their burden under Rule 702. "Although true that rejecting expert testimony is the exception rather than the rule, this does not mean that the Court will refrain from granting a motion to exclude expert testimony in an

appropriate case, such as when the expert is not qualified to testify on a particular subject or the underlying methodology is unreliable." *Nat'l Western Life Ins. v. Western Nat. Life Ins.*, No. A-09-CA-711, 2011 WL 692976, at *3 (W.D. Tex. Feb. 18, 2011); *accord Cook v. Rockwell Intern.*, 580 F. Supp. 2d 1071, 1083 (D. Colo. 2006) ("[T]he rejection of expert testimony is the exception rather than the rule. That being said, the proponent of an expert witness must demonstrate that the expert's proffered testimony meets Rule 702's requirements.").

**5. Plaintiffs' Experts Cross the Line into Improper Narrative Testimony**

Plaintiffs contend that their experts may introduce narrative testimony in order to synthesize voluminous evidence. But even they concede that "an expert must do *more* than simply construct a factual narrative based on record evidence." Pls. Br. 7-8. Expert testimony is admissible only if it will help the jury "*understand* the evidence." *Newell Rubbermaid, Inc. v. Raymond Corp.*, 676 F.3d 521, 572 (6th Cir. 2012) (emphasis added). For this reason, expert testimony may not be admitted "solely for the purpose of constructing a factual narrative based upon record evidence." *Rheinfrank v. Abbott Labs., Inc.*, No. 1:13-cv-144, 2015 WL 13022172, at *9 (S.D. Ohio 2015). An expert also cannot offer a "historical commentary of what happened," because such testimony is "properly presented through percipient witnesses and documentary evidence, not expert narrative." *In re Welding Fume Prods. Liab. Litig.*, No. 1:03-CV-17000, 2010 WL 7699456, at *42 n. 168 (N.D. Ohio June 4, 2010) (quotations omitted).

Here, Plaintiffs' experts cross the line. Their expert opinions are replete with impermissible "narrative gloss." *United States v. Kilpatrick*, 798 F.3d 365, 381 (6th Cir. 2015). Courts throughout the country have repeatedly recognized that "an expert may not provide narrative testimony pulled directly from the record without some analysis, opinion, or expertise." *Allen v. Am. Capital Ltd.*, 287 F. Supp. 3d 763, 804 (D. Ariz. 2017); *see also, e.g.*, *In re Rezulin Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (rejecting a portion of an expert

report presenting history of a medication for no purpose but to "provide an historical commentary of what happened"); *In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871 (E.D. Ark. 2008) (rejecting testimony that "was simply a regurgitation of an exhibit"). Expert testimony of this sort is inadmissible because "[i]t is not 'helpful' when a witness, lay or expert, forms conclusions for a jury that the jurors are competent to reach on their own." *Kilpatrick*, 798 F.3d at 381.

**6. Statistical Analysis Must Be Reliable**

Plaintiffs also assert that statistical analysis generally is an appropriate form of expert opinion. *See* Pls. Br. 9. Of course. But any such analysis still must comport with the requirements of Rule 702. A statistical analysis must be reliable, and therefore cannot use "assumptions and estimates as inputs that [are] 'implausible and inconsistent with record evidence.'" *In re Southeastern Milk*, 739 F.3d at 280 (quotation source omitted). Moreover, any conclusions drawn therefrom must be tethered to the data. *See McKesson Corp.*, 2019 WL 3532179, at *4 ("Although trained experts commonly extrapolate from existing data . . . nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.") (quoting *Joiner*, 522 U.S. at 146). And perhaps most fundamentally, the expert conducting the statistical analysis must be qualified to do so. *See, e.g.*, *Reid v. Albemarle Corp.*, 207 F. Supp. 2d 499, 506 (M.D. La. 2001) (declining to admit "plaintiffs' retained expert statistical witness [who] was not qualified . . . to express expert opinions on a statistical analysis").

**7. The Court's "Broad Discretion" Does Not Permit the Admission of Unreliable Expert Opinions**

Plaintiffs also seek to avoid meaningful scrutiny of their experts by observing that district courts have "broad discretion" in admitting expert testimony. *See* Pls. Br. 9. That is true enough. While Plaintiffs are correct that a district court's rulings under Rule 702 are reviewed for abuse of

discretion, they neglect to mention that a district court abuses that discretion by admitting unreliable or irrelevant evidence. *See Romberio v. Unumprovident Corp.*, 385 Fed. Appx. 423, 428 (6th Cir. 2009); *accord McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1239 (11th Cir. 2005) ("A trial court, however, abuses its discretion by failing to act as a gatekeeper."). District courts that do so invite reversal. *See, e.g.*, *Estate of Barabin v. AstenJohnson*, 740 F.3d 457, 464 (9th Cir. 2014) ("The district court abused its discretion by admitting the expert testimony without first finding it to be relevant and reliable under *Daubert*."); *McClain*, 401 F.3d at 1239 (trial court "abused its discretion by admitting the experts' testimony" that "failed to satisfy the standards of reliability required under *Daubert* and its progeny"); *Goebel v. Denver & Rio Grande Western R.R.*, 215 F.3d 1083, 1089 (10th Cir. 2000) (similar).

In short, Plaintiffs' seven additions to Defendants' *Daubert* roadmap do not excuse the defects that permeate their proposed expert opinions. And tellingly, Plaintiffs' roadmap response does not even attempt to address the fact that their proposed expert opinions are independently inadmissible as unfairly prejudicial or confusing under Rule 403. *See* Defs. Roadmap Br. at 7.

## II. REPLY TO PLAINTIFFS ROADMAP OF THEIR EXPERTS

### A. Summary of Replies Relating to Plaintiffs' Experts on Causation

***Meredith Rosenthal.*** Meredith Rosenthal purports to establish that Defendants' marketing caused an increase in the number of opioid prescriptions written across the county. Her opinions, however, do not fit the issues in this case and rely on a flawed methodology. Indeed, her entire opinion centers on the false assumption that ***all*** manufacturer detailing to prescribers was fraudulent. Plaintiffs double-down on this flawed narrative by claiming that they will prove this to be so, and also will prove that every single opioid prescription written after Defendants began marketing opioids for chronic noncancer pain was infected by fraud. The evidentiary record—including testimony from Plaintiffs' own experts—disproves Plaintiffs' novel, incredible theory.

Even so, Rosenthal's regression analysis includes all detailing visits—regardless of whether they were lawful or unlawful, and regardless of their substance and context. Her model fails to tie to any cognizable liability theory or the facts in evidence, and is thus unhelpful to the trier of fact. Beyond these "fit" issues, Plaintiffs have failed to offer a credible defense of Rosenthal's flawed methodology, including her "negative depreciation rate," which suggests that a detailing visit to a doctor will cause the doctor's opioid prescribing to increase exponentially into perpetuity. Her methodology suffers from other incurable flaws, as well. And once Rosenthal's testimony falls, so fall Plaintiffs' other causation experts who depend on her flawed opinions.

***David Cutler.*** David Cutler purports to "estimate" the harms caused by Defendants' marketing and distribution of prescription opioids in the Track One Counties. Yet Plaintiffs do not dispute that Cutler did not measure the relationship between alleged Defendant misconduct and Plaintiffs' alleged harms. Instead, at most, Cutler purports to show a nationwide average correlation between shipments of all prescription opioids (by Defendants and non-defendants alike) and all opioid mortality. That opinion is irrelevant and unreliable for several reasons. *First*, Cutler's models do not measure the relationship between Defendants' alleged misconduct and alleged harms in the Track One Counties because Cutler does not isolate alleged harms actually caused by shipments by Defendants that should have been blocked or were triggered by improper marketing, as opposed to shipments for legitimate medical need. Rather, Cutler measures an average, national relationship between ***all*** shipments and harms, and then simply assumes without any stated support that the average, national relationship generated by his all shipment regression holds in Cuyahoga and Summit Counties. Then, instead of actually trying to link alleged misconduct to harms, Cutler relies entirely on other experts or counsel—whose opinions are equally flawed and subject to exclusion—to try to create that link. But simply multiplying the

"average" impact generated from Cutler's national, all shipments model by inputs provided by other experts or counsel cannot isolate the harm (if any) caused by Defendants' alleged misconduct. *Second,* Plaintiffs' only defense of Cutler's multiplication of a variety of aggregate, national-level estimates to attribute complex, multi-faceted societal harms in the Track One Counties to alleged Defendant misconduct is that courts have in unique cases allowed aggregate proof models. But Plaintiffs cannot point to a single instance in which a court has permitted an opinion with the layered nature of Cutler's analyses and combination of so many Defendants. *Finally*, the unreliable inputs, speculative assumptions, and unreliable data included in Cutler's models render his conclusions unreliable and inadmissible.

***Plaintiffs' "Gateway" Hypothesis Experts.*** Relying on their incorrect assertion that an expert's conclusions are irrelevant to the *Daubert* analysis, *see supra*, Plaintiffs argue that Drs. Lembke, Keyes, and Gruber have properly relied on scientific literature to opine that there is a "clear, causal link" between prescription opioid use and the abuse of heroin and illicit fentanyl (the "Gateway hypothesis"). But none of the peer-reviewed studies on which these experts rely—including Dr. Keyes's own published work—supports this extreme position. The gap between the literature and the conclusions here is too great, and the testimony mirrors the type of testimony the Supreme Court held inadmissible in *General Elec. Co. v. Joiner*, 522 U.S. 136 (1997).

***Mark Schumacher, Anna Lembke, and Katherine Keyes's Marketing Causation Opinions.*** Plaintiffs' Opposition makes numerous concessions showing that the marketing causation opinions of Schumacher, Lembke, and Keyes should be excluded. As an initial matter, Plaintiffs concede that the three have no education, training, or experience in marketing—much less pharmaceutical marketing. Nor do they have prior experience conducting any marketing-

based causation analyses. In fact, Keyes did not even review any marketing materials in this case. They are not qualified to give their causation opinions.

Likewise, they have no methodology: their opinions merely *assume* a causal effect between Defendants' alleged false marketing and the opioid abuse crisis. Plaintiffs, for instance, do not dispute that none of the three experts has conducted any statistical or data analysis in reaching their causation conclusions; none has interviewed any Ohio prescribers or otherwise attempted to determine whether any prescribers received Defendants' allegedly false marketing and, if so, how it affected their prescribing decisions (if at all); and none has accounted for numerous other acknowledged factors that led to an increase in opioid morbidity and mortality. Rather, Plaintiffs' expert opinions rest solely upon a cursory review of literature showing that marketing can increase sales of medicines. This literature, however, consists of nothing more than generalized studies of pharmaceutical marketing that do not examine *these* manufacturers' marketing of *these* opioid medications or any of the effects of any alleged false marketing *in Ohio* (which Plaintiffs also do not dispute). In fact, Plaintiffs concede that their experts failed to consider each Defendant's marketing materials independently to determine any causal effects. Given the lack of any causation methodology, their speculative causation testimony is unreliable and would unfairly prejudice a jury. It should be excluded.

***Jonathan Gruber.*** Jonathan Gruber's key opinions are graphical depictions of incidence statistics (for opioid use disorder (OUD), opioid mortality, and crime) comparing U.S. counties in the top and bottom quartiles for prescription opioid shipments. From these graphs, Gruber seeks to conclude that prescription opioid shipments cause OUD, mortality, and crime. But he performs no analysis by any accepted methodology to support his causal conclusions, and relies instead on what his graphs might misleadingly suggest to a lay jury. The county quartiles he uses, moreover,

do not even include Cuyahoga and Summit Counties, and he undertakes no analysis to determine whether the causal conclusions he draws hold in those counties. In their Opposition, Plaintiffs claim that Gruber performs a regression analysis, but hide the fact that his regression is completely unrelated to his key graphics and causal conclusions. Even if these flaws were not dispositive, Gruber addresses ***all*** shipments together, proper and improper, and makes no effort to address any alleged Defendant misconduct or whether such misconduct caused any harm to the Counties. His opinions therefore are neither reliable nor relevant, and should be excluded.

B. **Summary of Replies Relating to Plaintiffs' Experts on Liability -- Marketing**

***David Egilman*.** Plaintiffs have abandoned Egilman as an expert.

***David Kessler and Matthew Perri.*** Perri's opinions are inadmissible because they lack a reliable methodology and do not "fit" the facts of the case. His report relies on vague "principles of marketing," which Plaintiffs now concede are "not a methodology." *See* Opp. at 14. Nevertheless, Plaintiffs claim that Perri's opinions are admissible because he used a "case study methodology," but neither Perri nor Plaintiffs have explained anywhere what this "methodology" entails or how Perri applied it to the evidence. This makes Perri's approach nothing more than a subjective black box and, therefore, inherently unreliable. His opinion that Defendants "failed to adhere to industry standards" also does not "fit" the facts of the case because it relies on the critical, but faulty, assumption that ***all*** of Defendants' marketing was false or misleading—a theory Plaintiffs disavowed to survive a motion to dismiss on preemption grounds.

Perri, and Kessler, also seek to present inadmissible narrative testimony and opinions about Defendants' states of mind. As explained above, experts cannot be used as vehicles to sum up facts and documents that speak for themselves. Plaintiffs' argument that experts can ***rely*** on documents is irrelevant because Kessler and Perri seek to do much more than that by presenting the ***contents*** of those documents. Likewise, while experts can present facts from which the ***jury***

can infer intent or knowledge, the proffered testimony goes far beyond that by offering the experts' ***own*** opinions on those questions.

Finally, Kessler's testimony is also fatally flawed because he invades the province of the Court by offering legal opinions, seeks to offer opinions about Noramco that were not previously disclosed, and lacks relevant training or experience in the area of pharmaceutical marketing.

**C. Summary of Replies Relating to Plaintiffs' Experts on Liability -- Diversion**

***Seth Whitelaw.*** Whitelaw's proposed testimony should be excluded because Whitelaw lacks any relevant "knowledge, skill, experience, training, or education" to qualify as an expert in suspicious order monitoring and because the methodology Whitelaw relies on to evaluate certain Defendants' suspicious order monitoring programs is unreliable. Whitelaw lacks the "knowledge, skill, experience, training, or education" to serve as an expert because he has no relevant experience with controlled substances, the Controlled Substances Act, or the Drug Enforcement Agency, and thus is unqualified to testify as an expert on DEA suspicious order monitoring programs. Whitelaw's methodology is unreliable because the foundation of his analysis—the Federal Sentencing Guidelines—is not used by DEA or industry to develop or evaluate DEA suspicious order monitoring programs. Plaintiffs do not dispute or even address testimony from DEA that the Federal Sentencing Guidelines are not used to evaluate suspicious order monitoring programs.

Plaintiffs' attempt to recast Whitelaw's opinions as "a holistic assessment of Defendants' compliance programs" to mitigate his complete lack of qualifications fails. Whitelaw's opinions are not general compliance opinions because he analyzes only DEA suspicious order monitoring programs and offers no opinions on any other compliance program of the Defendants. Whitelaw is unqualified as an expert; his opinions are unreliable; and, as a lawyer, he purports to opine on ultimate legal issues in this case. Whitelaw's opinions should be excluded.

***James Rafalski.*** Defendants moved to exclude five opinions offered by Plaintiffs' suspicious order monitoring (SOM) expert James Rafalski, because he provided no basis for those opinions. In response, Plaintiffs retracted two of those opinions. Plaintiffs now concede that, contrary to his deposition testimony, Rafalski will "not offer opinions about the number of orders that were in fact diverted." Opp. at 2 (emphasis in original). Plaintiffs also concede that Rafalski's opinions regarding his so-called "key components" of a SOM system are not required by DEA regulations. To avoid surprise at trial, the Court should rule that Plaintiffs are precluded from offering these retracted opinions. With respect to the remaining three challenged opinions, Plaintiffs still have not pointed to any admissible bases to support them, and they continue to rely on undisclosed legal guidance from DEA. Plaintiffs do not dispute that Rafalski was required to disclose all bases for his opinions in his report under Rule 26, or that the Court is required to strike opinions where no basis has been disclosed under Rule 37. The Court should rule that Rafalski may not offer these three challenged opinions at trial, either.

***Craig McCann.*** Plaintiffs offer no meaningful defense of McCann's use of order-flagging algorithms as a means to identify the "suspicious orders" shipped to the Track One Counties when those algorithms do not reflect a legal duty owed by Defendants. Indeed, they concede that no Defendant had a duty to use McCann's algorithms, arguing instead that one of the methods—McCann's "Six Month Trailing Threshold" or SMTT—provides an "estimate" of the orders Defendants should have identified through any reliable suspicious order system, whatever its precise form. That argument depends on expert opinion that was never offered by McCann, Rafalski, or any other expert. At the same time, their position depends upon there being an obligation to use the SMTT method because that is the starting point for McCann's assumption that Defendants "did not perform adequate due diligence" on orders that triggered that

model. Plaintiffs have no answer to this untenable contradiction. Because Defendants had no obligation to use McCann's methods, his analysis does not fit the facts of the case.

***Lacey Keller.*** As Defendants' opening motion explained, Keller takes over a dozen SOM criteria from a number of different entities and applies them all to IQVIA prescription data, regardless of whether any criteria is appropriate for any Defendant's business and regardless of the fact that DEA has never required monitoring of IQVIA data. Plaintiffs contend that Keller's analysis somehow sheds light on Defendants' obligations under the Controlled Substances Act, but concede that she offers no opinions on that issue. They offer no justification for her universal application of SOM criteria developed as part of individual companies' customized compliance programs. And they misread authorities stating that Defendants would not have had to report any orders that subsequent investigation revealed to be legitimate. Nor do Plaintiffs defend Keller's choice to use 2018 IQVIA that was created for this litigation, that is not the same data that actually was available over the time period Keller analyzes. Plaintiffs likewise fail to justify Keller's "small labeler" analysis, which rests on the unsupportable assumption that the moment a labeler with a minuscule market share reports a physician to law enforcement, that physician immediately stops prescribing all opioid medications forever. Finally, Keller concedes that she cannot reliably "trace" specific orders placed with Defendant Mallinckrodt downstream to their ultimate ends as her report claims, but nevertheless opines that her testimony might still be useful as an "estimate" for the jury's consideration. These fatal defects render Keller's analysis unreliable and irrelevant to any material issue in this litigation, and hence inadmissible.

### D. Summary of Replies Relating to Plaintiffs' Experts on Damages / Abatement

***Thomas McGuire.*** Plaintiffs continue to argue that Thomas McGuire offers a valid damages opinion, even though he does not identify any increased out-of-pocket expenses caused by Defendants' alleged misconduct—not a single new employee hired, not a single hour of

overtime paid, not a single item purchased. McGuire's theory—that "reallocation[s]" of existing-employee time to opioid-related tasks are "damages"—is contrary to Ohio law and this Court's prior order on the topic, Dkt. 1203 at 19-20. McGuire's damages opinion not only fails to "fit" the issue of damages but also is unreliable. Despite Plaintiffs' claim that McGuire's methodology need not be testable, the Sixth Circuit has said that "they key question" in admitting a damages opinion is "whether it can be (and has been) tested." McGuire's damages determinations—for which he provides no guiding standards—are not testable, not reliable, and inadmissible.

***Abatement Experts.*** Plaintiffs' Opposition to Defendants' motion to exclude Plaintiffs' "abatement" experts is an exercise in deflection and distraction. Plaintiffs largely concede the problems Defendants identified in their motion, but then simply say they do not matter. And, instead of addressing the specifics of Defendants' arguments explaining why these expert reports are neither relevant nor reliable—and thus flunk the *Daubert* test—Plaintiffs simply point to the experts' qualifications and to large swaths of their deposition testimony and reports that are tangential to the specific *Daubert* flaws identified by Defendants. Making matters worse, Plaintiffs also misconceive the nature of the remedy available in this case. Contrary to Plaintiffs' assertions, abatement involves stopping the nuisance-producing conduct—not addressing injuries purportedly suffered by individuals as a result of the nuisance. Given these shortcomings, Plaintiffs' abatement expert opinions should be rejected.

In sum, Plaintiffs have failed to satisfy *Daubert*, and the Court should exercise its gatekeeping function and exclude the testimony challenged by Defendants.

Date: August 16, 2019 Respectfully submitted,

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[1] Teva Pharmaceutical Industries Ltd., Allergan plc, and Mallinckrodt plc are respectively an Israeli corporation, Irish holding company, and an Irish company that are not subject to and contest personal jurisdiction for the reasons explained in their motions to dismiss for lack of personal jurisdiction; they are specially appearing to join this motion and, thus, they do not waive and expressly preserve their pending personal jurisdiction challenges.

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